

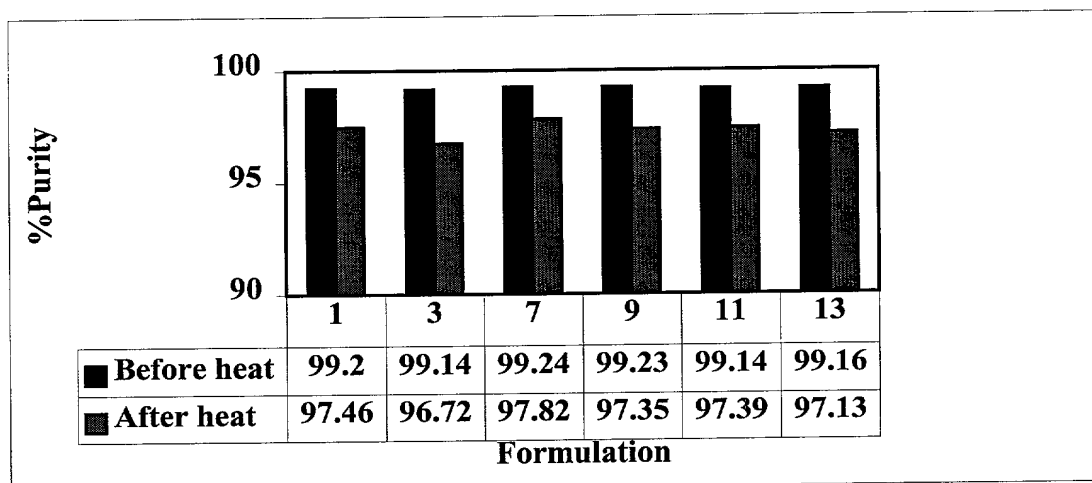
Title: GLP-2 FORMULATIONS

Inventor(s): Indu J. Isaacs

Appl. No.: Not yet assigned

Atty. Docket No. 016777/0454

Figure 1. Amino acids screening in buffers using heat stress.



Formulation

1. 10 mM Phosphate, 10 mM Glu
3. 10 mM Phosphate, 10 mM Citrate
7. 10 mM Phosphate, 10 mM Ser
9. 10 mM Phosphate, 10 mM Pro
11. 10 mM Phosphate, 10 mM His
13. 10 mM Phosphate, 10 mM Gly

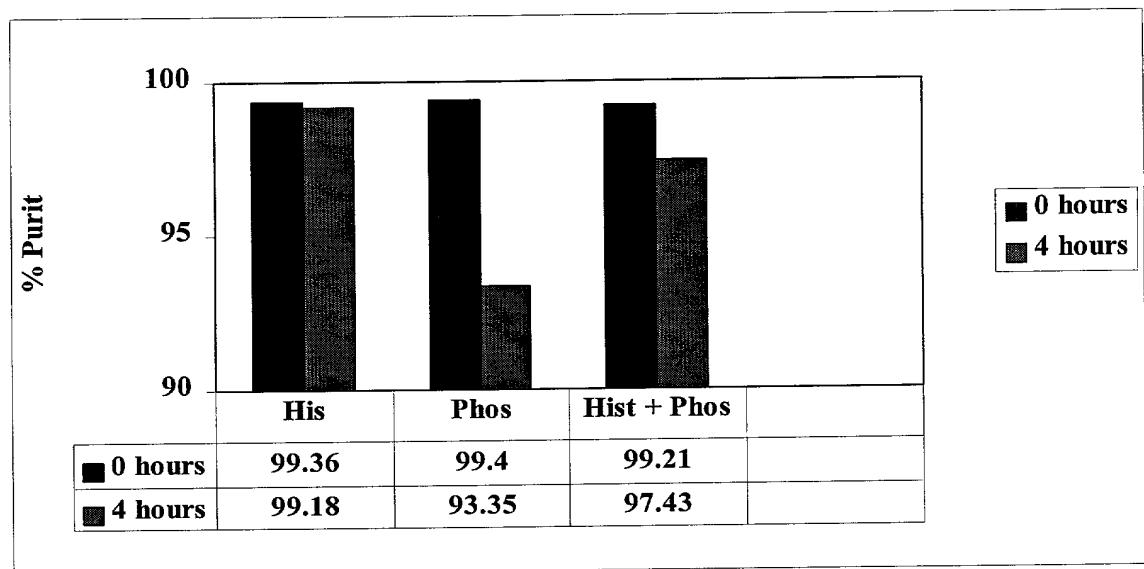
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Figure 2. Screening of buffers using heat stress.



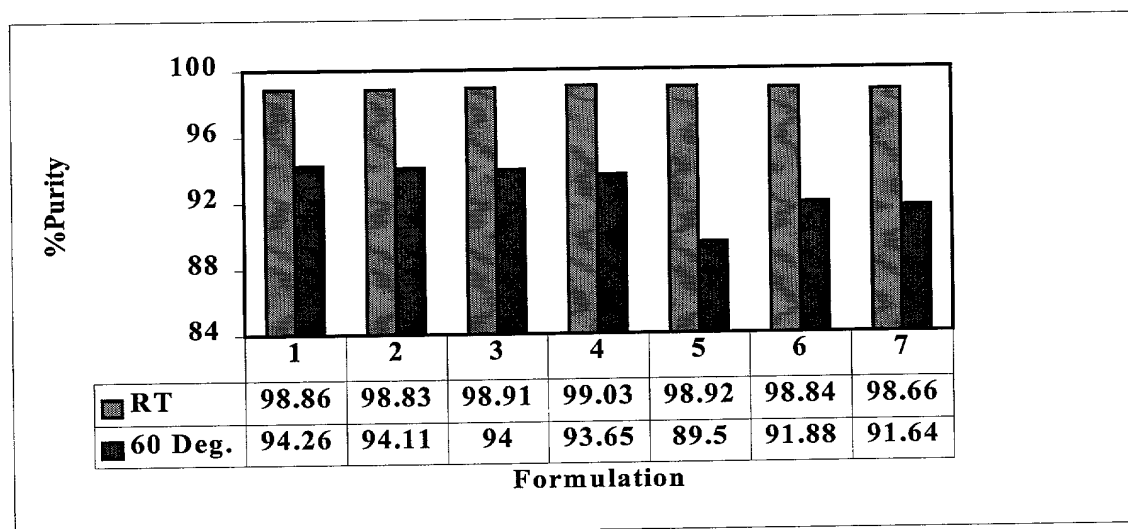
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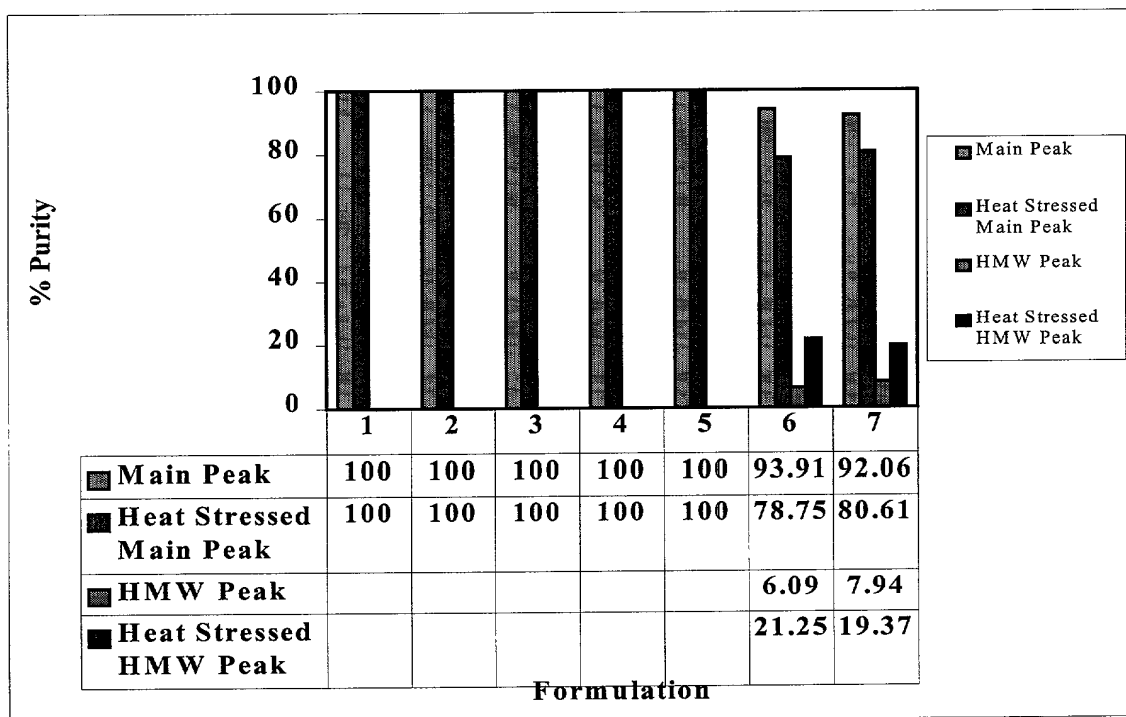
Figure 3. Screening of Bulking agents analyzed by RP-HPLC.



Formulation

1. 25 mM Histidine, 35 mM phosphate, 3% Mannitol
2. 50 mM Histidine, 35 mM phosphate, 3% Mannitol
3. 75 mM Histidine, 35 mM phosphate, 3% Mannitol
4. 25 mM Histidine, 25 mM phosphate, 3% sucrose
5. 25 mM Histidine, 25 mM phosphate, 3% trehalose
6. 25 mM Histidine, 25 mM phosphate, 3% maltose
7. 25 mM Histidine, 25 mM phosphate, 3% lactose

Figure 4. Bulking agents analyzed by SE-HPLC.



Formulation

1. 25 mM Histidine, 35 mM phosphate, 3% Mannitol
2. 50 mM Histidine, 35 mM phosphate, 3% Mannitol
3. 75 mM Histidine, 35 mM phosphate, 3% Mannitol
4. 25 mM Histidine, 25 mM phosphate, 3% sucrose
5. 25 mM Histidine, 25 mM phosphate, 3% trehalose
6. 25 mM Histidine, 25 mM phosphate, 3% maltose
7. 25 mM Histidine, 25 mM phosphate, 3% lactose

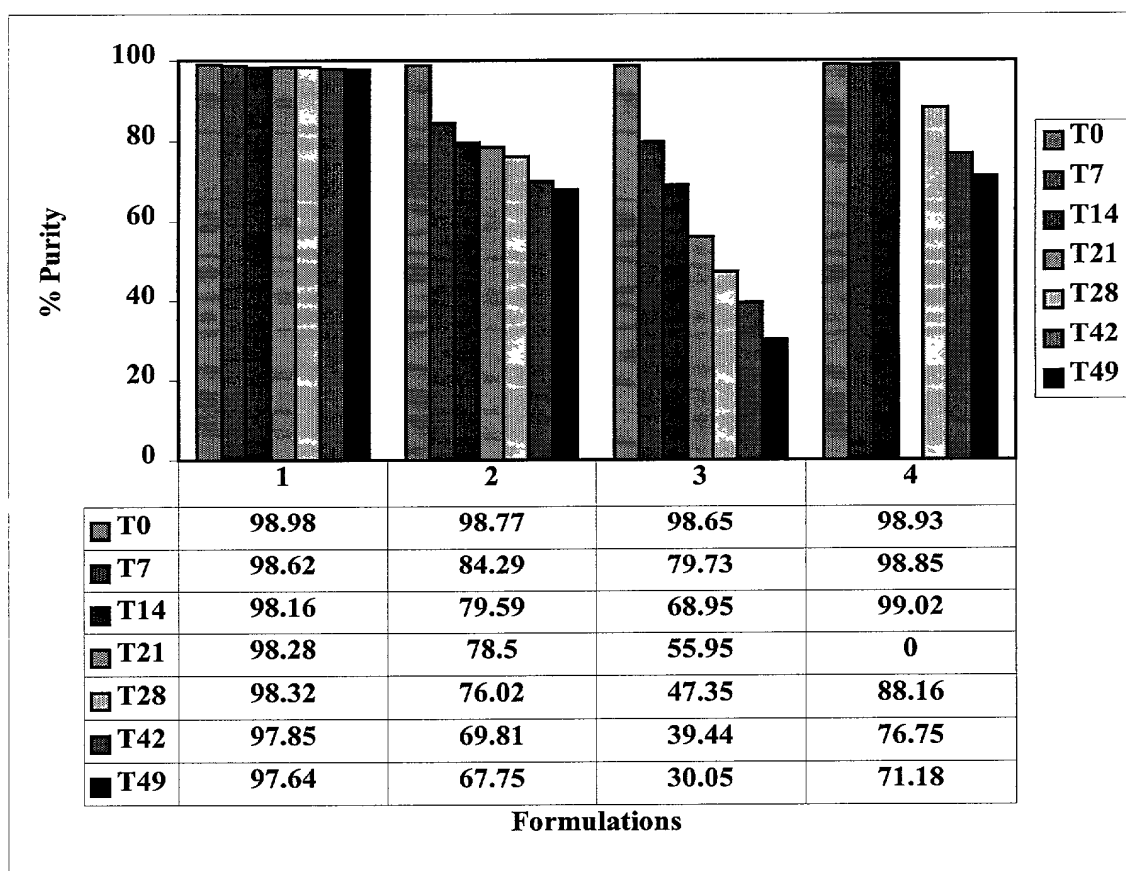
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Figure 5. Stability of liquid formulations stored at 4 °C.



Formulations

1. 35 mM Phosphate, 50 mM Histidine, 3% Mannitol, pH 7.4
2. 35 mM Phosphate, 50 mM Histidine, 5% Sucrose, pH 7.4
3. 35 mM Phosphate, 25 mM Lysine, 3% Mannitol, pH 7.4
4. 35 mM Phosphate, 25 mM Lysine, 5% Mannitol, pH 7.4

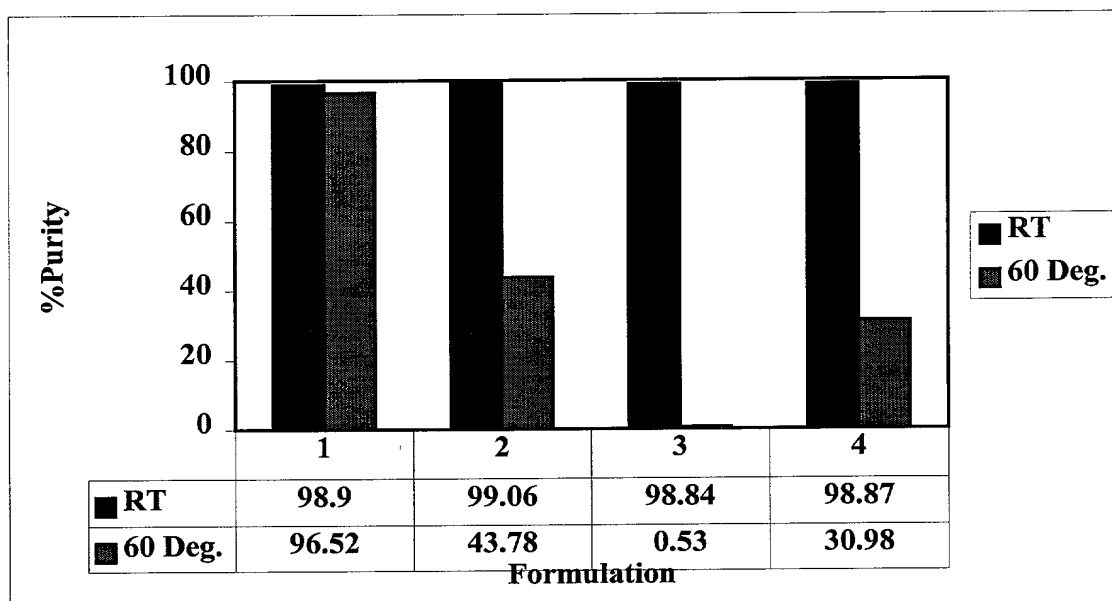
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Figure 6. Heat stressed samples.



Formulations

1. 35 mM Phosphate, 50 mM Histidine, 3% Mannitol, pH 7.4
2. 35 mM Phosphate, 50 mM Histidine, 5% Sucrose, pH 7.4
3. 35 mM Phosphate, 25 mM Lysine, 3% Mannitol, pH 7.4
4. 35 mM Phosphate, 25 mM Lysine, 5% Mannitol, pH 7.4